

# THE SKIN CANCER FOUNDATION

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July 8, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. 98N-1170**

## **Medical Devices: Sunlamp Products Performance Standard**

The Skin Cancer Foundation strongly supports the need for updated performance standards for sunlamp products. Current regulations were enacted in 1986, and since that time, our knowledge of the hazards of these devices has increased. It is now abundantly clear these devices lead to an increase in visible damage to the skin (photoaging) and skin cancer. In a medical setting, phototherapy units have been beneficial for a variety of dermatologic diseases. Other than these dermatologic uses, there is no credible evidence these devices provide any benefit other than cosmetic tanning. With any medical device or treatment, one must weigh the risks versus the benefits to determine if in fact the device or treatment is a reasonable choice. In the case of cosmetic indoor tanning lamps, the risks are clear and profound, while there are no benefits other than the short-lived cosmetic appearance. Therefore, the use of these devices is not reasonable. However, if they are going to be available, it is best that consumers are well informed so as to make an informed choice, and that the devices are used as safely as possible. We support the FDA's proposal to update warning statements and to highlight the risk of skin cancer, including melanoma.

## **Risks of Use**

### Short Term Risks

There are a number of short term risks from indoor tanning that can be minimized by more cautious use of the equipment. Certainly it is in the interest of the commercial operators to minimize adverse outcomes, so this is an area where all parties can agree. Screening, and exclusion, of clients with 1) history of photosensitive diseases such as lupus, porphyria, and rosacea 2) current use of photosensitizing medications 3) no children under the age of 18. This last point is particularly important as there is credible evidence that the ultraviolet light damage done to the skin in childhood and adolescence is more carcinogenic for melanoma and basal cell carcinoma than that received as an adult. Patrons must

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be informed that skin phototypes I and II, those who always sunburn and never tan or who sunburn first and later tan following sun exposure, can expect the same outcome from indoor tanning.

Responsible operation by the owners of the equipment may also increase safety. Protective eyewear must be provided to all patrons and its use mandatory. Operators, not clients, should control the timers on the devices, although a user cutoff switch must be in the unit. Acceptable timer intervals are a difficult area as there are now a variety of bulbs with a variety of spectral outputs on the market, and blanket statements about time intervals will not apply to all. Current regulations specify the manufacturer's recommendation determines maximal exposure time. However, if different bulbs than those originally envisioned by the manufacturer are installed, then exposure time becomes unpredictable. We propose operators regularly monitor and document the output of their devices with UV photometers, as is currently performed with medical phototherapy units, and that tables are developed that in turn will determine allowable exposure times. We propose such a table incorporate a variety of biologic markers of UV damage and not sunburn alone as an endpoint.

#### Long Term Risks

The long-term risks of sunlamp use have become clearer since the 1986 regulations were enacted. At that time, there was a controversy over the claim that indoor tanning lamps were principally UVA emitting, and thus safer than natural sunlight. This turned out to be a false claim, as it has been demonstrated in experimental animals that UVA by itself can induce sunburns, photoaging, and squamous cell skin cancer. Furthermore, the bulbs were never pure UVA anyway. This is now an irrelevant debate, as bulbs in current use are a mixture of UVA and UVB. While the percentage UVA and UVB in sunlight varies with time and place, the current mixture in sunlamp bulbs is certainly in the range of normal variance and is not significantly different from sunlight. Hence the claim that sunlamps are safer than the sun is clearly untrue and should not be allowed in advertising.

Indoor sunlamps are used to change the cosmetic appearance of the skin by tanning. The great irony of this cosmetic treatment is that the cosmetic appearance of the skin is significantly worsened in the long run by these devices. Exposure to ultraviolet radiation leads to wrinkled, leathery, discolored skin known as photoaging. These changes are not a normal component of the aging process, but rather a result of ultraviolet light exposure. In experimental animals, these changes are produced by both UVA and UVB, and are preferentially produced by a given dose of ultraviolet radiation being given in many small doses (such as an indoor tanner would receive) as opposed to a few large exposures (sunburn). Since cosmetic improvement is the goal of sunlamp users, it is only reasonable they be clearly informed that "sunlamps cause wrinkles".

Skin cancer represents the greatest risk from the use of sunlamps. The three common types of skin cancer, basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and melanoma, are all caused by ultraviolet radiation. Over the last 50 years there has been a remarkable increase in the incidence of skin cancer, and certainly intentional cosmetic tanning is a

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factor. While all parties agree that ultraviolet radiation causes skin cancer, there remains some uncertainty about the action spectra and dose/time relationships. This uncertainty in no way negates the fact that ultraviolet radiation causes skin cancer and should not be used as an excuse to promote tanning. Squamous cell carcinoma remains the best studied skin cancer, because animal models exist which allow laboratory investigation. While UVB is much more efficient than UVA in inducing SCC, both can do so. In the case of basal cell carcinoma and melanoma, it remains unclear exactly where in the UV range the peak cancer-causing emissions lie. Since sunlight is a mixture of UVA and UVB, this is an academic question only; the ultraviolet spectrum contained in sunlight causes basal cell carcinoma and melanoma. Modern sunlamps are now a mixture of UVA and UVB meant to simulate the sun, and thus contain the same dangerous wavelengths.

Dose - time relationships are another area of controversy. Simply put, for a given dose of ultraviolet radiation, does it make a difference if the energy is given in many small doses such as might be experienced by an indoor tanner, or given in a few large doses such as might be experienced by someone receiving a sunburn? Since a variety of animals develop squamous cell carcinoma, this question can be answered experimentally. For the development of squamous cell carcinoma, many small doses of UV radiation are more carcinogenic than the same dose given in a few big doses. In other words, tanning is more carcinogenic for SCC than burning. There is also an animal model for photoaging, and the same relationship holds true: tanning causes greater photoaging than burning. There is no animal model for BCC or melanoma, hence this question cannot be simply answered. Epidemiologic studies have suggested childhood sunburns are the most carcinogenic exposures for both BCC and melanoma, but such retrospective epidemiologic studies remain controversial and imprecise. Much has been made of this "childhood burn" hypothesis by sunlamp advocates. They argue that since burns cause melanoma, tanning is harmless, and may even lower the incidence of cancer-causing sunburns by protecting the skin with melanin. However, the individuals at most risk for melanoma and other skin cancers are fair-skinned, sun-sensitive people. These high-risk people always sunburn first, then tan later or not at all. Thus for the highest risk groups, the "tans vs burns" debate is irrelevant. These people always burn first, and then tan poorly or not at all. Epidemiologic studies looking at melanoma and sunlamp use have produced mixed results. Four early studies found no relationship, while at least six more recent studies have shown a positive correlation between sunlamp use and melanoma. Four of these studies showed a dose-response relationship between sunlamps and melanoma.

In summation, the relationship between sunlamps and skin cancer is convincingly clear. Chronic low-dose exposure to ultraviolet radiation, received outdoors or from a sunlamp, has been experimentally demonstrated to cause squamous cell carcinoma and photoaging. The action spectrum and dosing schedule for UV-induced BCC and melanoma remains unclear, although there is a body of epidemiologic studies showing a correlation between melanoma and sunlamp use. A clear warning label needs to be prominently visible on tanning equipment with a simple message such as "tanning causes wrinkles and skin cancer".

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### **Benefits**

Advocates of the indoor tanning industry have recently promoted the health benefits of sunlamps. There is no evidence that any such benefits exist. However, we will review and discuss these claims.

As previously mentioned, there is a theory that melanoma is caused by childhood sunburns. Tanning advocates have argued that if these children were tan, they would not sunburn so easily, and thus indoor tanning before a beach vacation would actually be preventative. However, as previously mentioned, the most high-risk individuals, the fair-skinned and sun-sensitive, tan poorly or not at all. These individuals will only get what they are trying to avoid: a sunburn. For those who do tan, the protective effect from sunlight of a tan from a sunlamp is minimal at best. Furthermore, we know with certainty that the tanning process causes SCC and photoaging, and may possibly cause BCC and melanoma. Therefore, this is a health risk, not a health benefit.

A rather novel idea is that tanning prevents internal malignancy by increasing serum levels of vitamin D. This idea comes from the observation that the incidence or mortality of breast, colon, and prostate cancer decreases as one moves towards the equator. This observation is somewhat true, with notable exceptions such as the low colon cancer rate among the Japanese (a northern country) and among Eskimos. In our country, the geographic variability holds true for the northeast, but not for the northwest. From this geographic variation, the speculation was made that greater sun exposure in southern latitudes accounts for the lower rates. Many cancers vary in frequency from one region to another in ways that do not correlate with sun intensity. Diet, life style, racial variants, and chemical exposures are all variables. Despite the lack of any supporting evidence, these same researchers went on to speculate that increased sun exposure leads to increased levels of vitamin D in the body, and this accounts for the protective effect. It is true that vitamin D is manufactured in the skin in response to ultraviolet radiation. However, dietary supplements with vitamin D have not had any impact on cancer in several studies. Certainly, if vitamin D is ever shown to prevent cancer, then dietary supplements should be recommended. However, since no effect of vitamin D has been shown, to recommend tanning at the beach or in an indoor tanning salon to prevent cancer is clearly ill-advised at this point. It is our strong recommendation that no statements claiming health benefits from sunlamps be allowed.

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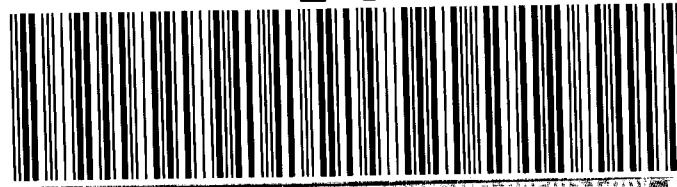
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